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10/535,545	05/18/2005	Eric Ferrandis	58767.000062	7587

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EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,545	FERRANDIS, ERIC	
	Examiner	Art Unit	
	LYNN BRISTOL	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 23-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23,24,37 and 38* is/are allowed.

6)☒ Claim(s) *10, 25-36, and 39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 10 and 23-44 are all the pending claims for this application.

2. Claims 2-5, 8 and 9 were cancelled, Claim 10 was amended and new Claims 23-44 were added in the Response of 3/30/09.

3. Claims 10 and 23-44 are all the pending claims under examination.

4. Applicants amendments to the claims have necessitated new grounds for objection and rejection. This action is FINAL.

Withdrawal of Rejections

Claim Rejections - 35 USC § 112, second paragraph

5. The rejection of Claim 10, lines 3-4 as being indefinite for the recitation "or by a sequence complementary to the polynucleotide sequence SEQ ID NO:9" is withdrawn. Amending the claim to delete the limitation in the Response of 3/30/09 overcomes the rejection.

6. The rejection of Claim 10, element a) in lacking antecedent basis for the limitation "the sequence complementary to the polynucleotide sequence...or SEQ.ID.NO. 13" is withdrawn. Amending the claim to delete the limitation in the Response of 3/30/09 overcomes the rejection.

Claim Rejections - 35 USC § 103

7. The rejection of Claims 2-5 and 8-10 under 35 U.S.C. 103(a) as being unpatentable over Ferrandis et al. (USPN 7385024; issued June 10, 2008; filed 2/26/02) in view of Campbell (Biology, 3rd Ed, the Benjamin/Cummings Publishing Company, Inc., 1993 (p. 321)) and Sambrook et al. (Molec. Cloning, Vol 2, Protocol 1, pp. 8.18-8.22 (2001)) is withdrawn.

Applicants' allegations on pp. 8-10 of the Response of 3/30/09 have been considered and are found persuasive. Applicants assert that the invention of the '024 patent and the instant claimed invention, were at the time the invention was made, owned by or subject to an obligation of assignment to the same person. The Statement of Common Ownership is acknowledged and entered.

NOTE: Applicants allege on p. 9 of the Response that under *In re Duel* a reference teaching the molecular weight of a protein and the first 19 amino acids in combination with Maniatis does not overcome the deficiencies of a reference that only discloses a partial sequence used in conjunction with a reference disclosing cloning protocols.

Under MPEP 2143 " The claimed invention in Ex parte Kubin, 83 USPQ2d 1410 (Bd. Pat. App. & Int. 2007), was an isolated nucleic acid molecule. The claim stated that the nucleic acid encoded a particular polypeptide. The encoded polypeptide was identified in the claim by its partially specified sequence, and by its ability to bind to a specified protein. A prior art patent to Valiante taught the polypeptide encoded by the claimed nucleic acid, but did not disclose either the sequence of the polypeptide, or the claimed isolated nucleic acid molecule. However, Valiante did disclose that by employing conventional methods such as those disclosed by a prior art laboratory manual by Sambrook, the sequence of the polypeptide could be determined, and the nucleic acid molecule could be isolated. In view of Valiante's disclosure of the polypeptide, and of routine prior art methods for sequencing the polypeptide and isolating the nucleic acid molecule, the Board found that a person of ordinary skill in the art would have had a reasonable expectation that a nucleic acid molecule within the claimed scope could have been successfully obtained. Relying on In re Deuel, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995), appellant argued that it was improper for the Office to use the polypeptide of the Valiante patent together with the methods described in Sambrook to reject a claim drawn to a specific nucleic acid molecule without providing a reference showing or suggesting a structurally similar nucleic acid molecule. Citing KSR, the Board stated that "when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." The Board noted that the problem facing those in the art was to isolate a specific nucleic acid, and there were a limited number of methods available to do so. The Board concluded that the skilled artisan would have had reason to try these methods with the reasonable expectation that at least one would be successful. Thus, isolating the specific nucleic acid molecule claimed was "the product not of innovation but of ordinary skill and common sense."

New Grounds for Objection

Claim Objections

8. Claim 10 is objected to because of the following informalities: In amending Claim 10, element (a), Applicants appear to have deleted a portion of the claim relating the expressed polypeptide with the phrase "at least one immunological and/or biological activity...". Appropriate correction is required.

New Grounds for Rejection

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 27, 33 and 41 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 27, 33 and 41, as written, do not sufficiently distinguish isolated cells comprising the vector from any *in vivo* cell modified with the vector including a transgenic human. The broadest reasonable interpretation of the claimed invention as a whole encompasses a human being (MPEP 2105).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

10. Claims 10, 25-36, and 39-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 is drawn to a process for producing a polypeptide from a vector-transformed host cell comprising a polynucleotide sequence with at least 95% homology to the sequence of SEQ ID NO: 9 or 13, where the expressed polypeptide has at least one immunological and/or biological activity characteristic of a protein binding human GHRH protein and is associated with the modulation of cell proliferation.

Claim 25 (and dependent Claims 26-30) are drawn to a polynucleotide having at least 95% identity to the sequence of SEQ ID NO:8 and where the polynucleotide encodes a protein at least one immunological and/or biological activity characteristic of a protein binding human GHRH protein and is associated with the modulation of cell proliferation.

Claim 31 (and dependent Claims 32-36) are drawn to a polynucleotide having at least 95% identity to the sequence of SEQ ID NO:9 and where the polynucleotide encodes a protein at least one immunological and/or biological activity characteristic of a protein binding human GHRH protein and is associated with the modulation of cell proliferation.

Claim 39 (and dependent Claims 40-44) are drawn to a polynucleotide having at least 95% identity to the sequence of SEQ ID NO:13 and where the polynucleotide encodes a protein at least one immunological and/or biological activity characteristic of a protein binding human GHRH protein and is associated with the modulation of cell proliferation.

The specification does not support a structure/ function correlation for the myriad polypeptides encompassed by the expressed polynucleotides having "at least 95% homology" to the sequence of the claimed SEQ ID NO: and the at least one immunological and/or biological activity characteristic of a protein binding human GHRH protein and is associated with the modulation of cell proliferation. Under the Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001) revised training materials 3/29/08), the claimed invention must meet the following criteria as set forth.

a) Actual reduction to practice: The specification discloses the cloning and isolation of the gene for heterocarpine which is a plant-derived ligand from Pilocarpus heterophyllus which binds to human growth hormone releasing hormone (GHRH). The specification discloses the following sequences corresponding to heterocarpine:

SEQ ID NO:8- cDNA for heterocarpine (p. 28);

SEQ ID NO:9- open reading frame of cDNA for heterocarpine (p. 30); and

SEQ ID NO:13- SEQ ID NO:9 having artificially undergone deletion of the initiation codon ATG and the stop codon (p. 34);

The specification makes a general disclosure for isolated fragments of a "polynucleotide being such that it encodes a polypeptide having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation" [0006]. The specification does not provide sufficient written description as to the structural features of the claimed genus of polynucleotides having at least 95% homology to the sequence of SEQ ID NOS: 8, 9 or 13 (and the encoded polypeptides) and the correlation between the chemical structure and function of the genus of encoded, expressed polypeptides, such as structural domains or motifs that "encode a polypeptide having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation."

b) Disclosure of drawings or structural chemical formulas: the specification and drawings do not show that applicant was in possession of the polynucleotides encoding a protein having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation.

c) Sufficient relevant identifying characteristics: the specification does not identify 1) a complete structure, ii) partial structure, iii) physical and/or chemical properties, or iv) functional characteristics coupled with correlation between structure and function for the genus of polynucleotides encoding a protein having at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation.

d) Method of making the claimed invention: the specification teaches cloning the plant-derived heterocarpine DNA.

e) Level of skill and knowledge in the art: the cloning of DNAs and domain "bashing" (i.e., generating deletion mutants for a parent protein) for identifying functional regions within proteins was well established at the time of the invention.

f) Predictability in the Art: the art does not appear to teach where within the heterocarpine sequence the region encoding "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation" would be found.

Generally, the art acknowledges that function cannot be predicted solely on structural similarity to a protein. Smith et al. (Nature Biotechnology 15:1222-1223 (1997)) teach that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. Brenner (Trends in Genetics 15:132-133 (1999)) argues that accurate inference of function from homology must be a difficult problem since assuming there are only about 1000 major gene superfamilies in nature, then most homologues must have different molecular and cellular functions.

Applicants have not demonstrated with sufficient evidence the genus of polynucleotides having at least 95% homology to the sequence of SEQ ID NOS: 8, 9 or 13 and encoding proteins having "at least one immunological and/or biological activity characteristic of a protein binding human GHRH and being associated with the modulation of cell proliferation". The ordinary artisan could reasonably conclude that

Applicants were not in possession of the claimed genus of polynucleotides, thus accordingly their expressed polypeptides, at the time of application filing.

Conclusion

11. Claims 23, 24, 37 and 38 are allowed. Claims 23, 24, 37 and 38 are drawn the sequences for primers and are free from prior art. The polynucleotide sequence of SEQ ID NO: 8, 9 and 13 is free from prior art.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lynn A. Bristol/
Examiner. Art Unit 1643
Temporary Full Signatory Authority